## PCT

## WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT) (51) International Patent Classification 6: WO 99/51209 (11) International Publication Number: A61K 9/22 A1 (43) International Publication Date: 14 October 1999 (14.10.99) (21) International Application Number: PCT/US99/06987 (81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, (22) International Filing Date: 31 March 1999 (31.03.99) GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, (30) Priority Data: 2 April 1998 (02.04.98) 09/053,491 US ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (71) Applicant: IMPAX PHARMACEUTICALS, INC. [US/US]; 30831 Huntwood Avenue, Hayward, CA 94544 (US). (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). (72) Inventors: TING, Richard; 38 Woodranch Circle, Danville, CA 94506 (US). HSIAO, Charles; 2012 Westbrook Lane, **Published** Livermore, CA 94550 (US). With international search report. (74) Agent: SUNG, Lawrence; Arter & Hadden, LLP, Suite 400K, Before the expiration of the time limit for amending the 1801 K Street, N.W., Washington, DC 20006 (US). claims and to be republished in the event of the receipt of amendments. (54) Title: PRESS COATED, PULSATILE DRUG DELIVERY SYSTEM SUITABLE FOR ORAL ADMINISTRATION

## (57) Abstract

A press coated, pulsatile drug delivery system suitable for oral administration having an immediate-release compartment, which contains a compressed blend of an active agent and one or more polymers, substantially enveloped by an extended-release compartment, which contains a compressed blend of the active agent and hydrophilic and hydrophibic polymers, can provide a substantially first order delivery of the active agent, interrupted by a timed, pulsed delivery of an increased amount of the active agent; and when the extended-release compartment is substantially enveloped by an optional instant-release compartment, can provide a dose sufficient to exceed the liver's metabolic capacity and to maintain therapeutic levels, preferably throughout a 24-hour period.